Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 162

Report Date:10/04/2007

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Columbus Laboratory Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute	058813803 059902703 050517405 059201205 059201305	08/16/99 08/12/02 08/05/02 07/15/98 01/20/00	729 729 729 729 729 730	50 (3) 50 (3) 50 (3) 50 (3) 50 (3)	22(681) 37(705) 33(703) 35(704) 31(702)	501.7 452.8 510.0 446.9 448.0	Benzophenone Chromium picolinate monohydrate Cresols 2-Methylimidazole 4-Methylimidazole
				Fen	nale		
Battelle Columbus Laboratory Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute	058813803 059902703 050517405 059201205 059201305	08/17/99 08/12/02 N/A 07/15/98 01/20/00	729 733 N/A 734 735	50 (5) 50 (5) 0 (0) 50 (5) 50 (5)	32(688) 36(702) 0(0) 40(707) 40(702)	348.7 314.7 N/A 320.6 311.3	Benzophenone Chromium picolinate monohydrate Cresols 2-Methylimidazole 4-Methylimidazole

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 163

			Male				Female	
All Organs: Benign Tumors								
		49/50 (98%) 49/50 (98%)	49/50 (98%) 50/50 (100%)	50/50 (100%)		42/50 (84%) 43/50 (86%)	45/50 (90%) 48/50 (96%)	
verall Incidence	Total	247/250 (98.8%)	Mean \ 98.8%	SD 1.1%	Total	178/200 (89%)	Mean 89%	SD 5.29%
All Organs: Malignant Tumors								
		33/50 (66%) 22/50 (44%)	27/50 (54%) 22/50 (44%)	23/50 (46%)		20/50 (40%) 19/50 (38%)	15/50 (30%) 19/50 (38%)	
Overall Incidence	Total	127/250 (50.8%)	Mean 50.8%	SD 9.44%	Total	73/200 (36.5%)	Mean 36.5%	SD 4.43%
All Organs: Malignant and Benign T	umors			((1000))		(2001)		
		50/50 (100%) 50/50 (100%)	50/50 (100%) 50/50 (100%)	50/50 (100%)		46/50 (92%) 45/50 (90%)	47/50 (94%) 48/50 (96%)	
verall Incidence	Total	250/250 (100%)	Mean 100%	SD 0%	Total	186/200 (93%)	Mean 93%	SD 2.58%
All Organs: Hemangioma								
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
All Organs: Hemangiosarcoma								
		0/50 (0%) 1/50 (2%)	2/50 (4%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 164

			Male				Female	
#All Organs: Hemangiosarcoma or He	mangioma							
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%) 3/250 (1.2%)	0/50 (0%) Mean 1.2%	SD 1.79%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Histiocytic Sarcoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 2/50 (4%)	
Overall Incidence	Total	0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 3/200 (1.5%)	2/50 (4%) Mean 1.5%	SD 1.91%
fAll Organs: Leukemia: Lymphocytic, Undifferentiated	Monocytic, N	lononuclear, or 27/50 (54%) 15/50 (30%)	19/50 (38%) 15/50 (30%)	15/50 (30%)		19/50 (38%) 6/50 (12%)	9/50 (18%) 9/50 (18%)	
Overall Incidence	Total	91/250 (36.4%)	Mean 36.4%	SD 10.43%	Total	43/200 (21.5%)	Mean 21.5%	SD 11.36%
All Organs: Malignant Lymphoma: Hi or Undifferentiated Cell T	istiocytic, Lyr			1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 165

			Male				Female	
#All Organs: Mesothelioma: Benign, M	Malignant, NOS							
		2/50 (4%) 2/50 (4%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignan								
_		2/50 (4%) 2/50 (4%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma								
		0/50 (0%) 2/50 (4%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
0010000.001110		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 1/200 (0.5%)	1/50 (2%) Mean 0.5%	SD 1%
#All Organs: Osteosarcoma or Osteor				•••••			•••••	
23.000.00		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/50 (4%) 3/250 (1.2%)	0/50 (0%) Mean 1.2%	SD 1.79%	Total	0/50 (0%) 1/200 (0.5%)	1/50 (2%) Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

CISION: OCIZOO7

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 166

			Male				Female	
Adrenal Cortex: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	
		0/50 (0%)	1/50 (2%)	0/30 (0/0)		5/50 (10%)	1/49 (2%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	8/199 (4.02%)	Mean 4.01%	SD 4.31%
Adrenal Cortex: Carcinoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Ganglioneuroma	•••••							
3		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Adrenal Medulla:	•••••							
Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/48 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Benign								
		8/50 (16%) 8/50 (16%)	8/50 (16%) 8/50 (16%)	8/50 (16%)		0/50 (0%) 0/49 (0%)	1/50 (2%) 2/48 (4%)	
Overall Incidence	Total	40/250 (16%)	8/50 (16%) Mean 16%	SD 0%	Total	3/197 (1.52%)	2/46 (4%) Mean 1.54%	SD 1.99%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Control Animal Groups Report Date:10/04/2007
RAL

Page: 167

			Male				Female	
Adrenal Medulla: Pheochromocytoma Co	omplex							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	
verall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/197 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma M								
·	J	0/50 (0%) 0/50 (0%)	3/50 (6%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	2/50 (4%) 1/48 (2%)	
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 2.68%	Total	3/197 (1.52%)	Mean 1.52%	SD 1.92%
Adrenal Medulla: Pheochromocytoma: B	Benign, Complex	x, Malignant, NOS 8/50 (16%) 8/50 (16%)	11/50 (22%) 10/50 (20%)	8/50 (16%)		0/50 (0%) 0/49 (0%)	3/50 (6%) 3/48 (6%)	
overall Incidence	Total	45/250 (18%)	Mean 18%	SD 2.83%	Total	6/197 (3.05%)	Mean 3.06%	SD 3.54%
Blood Vessel: Osteosarcoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
verall Incidence	Total	0/30 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Bone: Chondrosarcoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

CISION: OCIZOO7

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 168

			Male		Female	
#Bone: Chondrosarcoma or Chond	roma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0 0/50 (0%)	9%) 0/50 0/50	()	
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/200		
≇Bone: Chordoma						
		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2 0/50 (0%)	9%) 0/50 0/50	()	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8% SD 1.19		` ,	
Bone: Osteoma						
		0/50 (0%) 2/50 (4%)	0/50 (0%) 0/50 (0 0/50 (0%)	9%) 0/50 0/50	()	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8% SD 1.79		` ,	
Bone:						
Osteosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0 0/50 (0%)	%) 0/50 0/50	` ,	
verall Incidence	Total	0/250 (0%)	Mean 0% SD 0%		` ,	
Bone: Osteosarcoma or Osteoma						
		0/50 (0%) 2/50 (4%)	0/50 (0%) 0/50 (0 0/50 (0%)	9%) 0/50 0/50	()	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8% SD 1.79		(0.5%) Mean 0.5% SD 1%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 169

			Male				Female	
*Brain: Astrocytoma Malignant		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Ependymoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/30 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%
*Brain: Glioma Malignant								
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%
Brain: Granular Cell Tumor Beni	gn							
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 2/250 (0.8%)	2/50 (4%) 0/50 (0%) Mean 0.8%	0/50 (0%) SD 1.79%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%
Brain: Medulloblastoma Mal		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 170

			Male				Female	
*Brain: Meningioma Malignant		0/50 (00/)	0/50 /00/	0/50 (00/)		0/50 (00/)	0/50 (00/)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain:					•••••			
Meningioma: Benign, M	lalignant, NOS	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	, ,		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma Ber								
3 3 3 3 3 3 3 3 3 3	3	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain:								
Oligodendroglioma Mal	lignant	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0,00 (0,0)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain:					•••••			
Oligodendroglioma, Gli	oma, or Astroc	ytoma 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/30 (076)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

CISION: COLECCI

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 171

			Male				Female	
Clitoral/Preputial Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 2/50 (4%)	5/50 (10%)		3/50 (6%) 5/50 (10%)	10/50 (20%) 8/50 (16%)	
Overall Incidence	Total	8/250 (3.2%)	Mean 3.2%	SD 4.15%	Total	26/200 (13%)	Mean 13%	SD 6.22%
Clitoral/Preputial Gland: Carcinoma					••••			
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 3/50 (6%)	0/50 (0%) 2/50 (4%)	
Overall Incidence	Total	1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	3/50 (6%) 6/200 (3%)	2/50 (4%) Mean 3%	SD 2.58%
Clitoral/Preputial Gland: Carcinoma or Adenoma					•••••			
		1/50 (2%)	1/50 (2%)	5/50 (10%)		4/50 (8%)	10/50 (20%)	
Overall Incidence	Total	0/50 (0%) 9/250 (3.6%)	2/50 (4%) Mean 3.6%	SD 3.85%	Total	8/50 (16%) 32/200 (16%)	10/50 (20%) Mean 16%	SD 5.66%
Clitoral/Preputial Gland:						•••••		
Fibrosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/30 (0 /8)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 172

			Male				Female	
#Ear: Neural Crest Tumor								
Nedrai Orest Tullion		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Esophagus: Fibrosarcoma			•••••			•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Eye: Amelanotic Melanoma, Be	enign					•••••		
	J	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Eye: Melanoma Benign		•••••				•••••		
Meianoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	
hanall Includence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 40/
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Eye: Schwannoma Malignant		0/50 (00)	0/50 (00/)	4/50 (00/)		0/50 /00/	0/50 (00/)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 173

			Male				Female	
#Harderian Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Heart:								
Schwannoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	,		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Heart: Schwannoma Malignant								
		1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 174

			Male				Female	
#Intestine Large: Colon/Rect Adenoma	ım:							
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Recti Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rector Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Recti Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 175

			Male				Female	
#Intestine Small: Duodenum: Leiomyoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyosarcoma								
, , , , , , , , , , , , , , , , , , , ,		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Intestine Small: Site Unspecifi			•••••				•••••	
Carcinoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Untacting Compile City Hangacif								
Intestine Small: Site Unspecifi Carcinoma or Adenoma	iea:	(00)		2(22 (22)		(00)	2/22 (224)	
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

EISIOII. OCI2007

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 176

			Male				Female	
fIntestine Small: Site Unspec Leiomyoma	ified:							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspec Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Adenoma	•••••							
		1/50 (2%) 0/50 (0%)	1/50 (2%) 3/50 (6%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	2/49 (4%) 0/49 (0%)	
Overall Incidence	Total	6/249 (2.41%)	Mean 2.41%	SD 2.19%	Total	2/198 (1.01%)	Mean 1.02%	SD 2.04%
slets, Pancreatic:								•••••
Carcinoma		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/49 (0%)	
		0/50 (0%)	0/50 (0%)	(=75)		2/50 (4%)	0/49 (0%)	
overall Incidence	Total	2/249 (0.8%)	Mean 0.81%	SD 1.11%	Total	2/198 (1.01%)	Mean 1%	SD 2%
slets, Pancreatic: Carcinoma or Adenoma								•••••
		1/50 (2%) 0/50 (0%)	2/50 (4%) 3/50 (6%)	2/49 (4%)		0/50 (0%) 2/50 (4%)	2/49 (4%) 0/49 (0%)	
Overall Incidence	Total	8/249 (3.21%)	Mean 3.22%	SD 2.29%	Total	4/198 (2.02%)	0/49 (0%) Mean 2.02%	SD 2.33%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 177

			Male				Female	
Kidney: Pelvis and Trans Carcinoma	itional Epitheliu	m:						
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)	
verall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Trans Carcinoma or Adenom	itional Epitheliu							
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)	
verall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Trans Papilloma		m: 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
overall Incidence	Total	0/49 (0%) 0/247 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/195 (0.51%)	1/48 (2%) Mean 0.52%	SD 1.04%
		1/50 (2%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)	
verall Incidence	Total	1/247 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/195 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)	
Overall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

E131011. OCI2001

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 178

			Male				Female	
Kidney: Renal Tubule: Carcinoma or Adenoma			(00)	2/52 (224)		2/50 (00)		
		1/50 (2%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)	
Overall Incidence	Total	1/247 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/195 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)	
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/195 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Lipoma								
_ 		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)	
Overall Incidence	Total	0/49 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule:							•••••	
Liposarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		0/49 (0%)	0/48 (0%)	, ,		0/50 (0%)	0/48 (0%)	
Overall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Mesenchymal Tumor Benig								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/47 (0%) 0/48 (0%)	
Overall Incidence	Total	0/49 (0%)	0/46 (0 %) Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 179

			Male				Female	
Kidney: Renal Tubule: Nephroblastoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
		0/30 (0%)	0/30 (0%)	0/30 (0%)		0/50 (0%)	0/47 (0%)	
Overall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	
Overall Incidence	Total	0/49 (0%) 1/247 (0.4%)	1/48 (2%) Mean 0.42%	SD 0.93%	Total	0/50 (0%) 0/195 (0%)	0/48 (0%) Mean 0%	SD 0%
overall incluence	Total	1/247 (0.470)	Weatt 0.4276	3D 0.93%	Total	0/193 (076)	Weatt 070	30 0%
Liver: Cholangiocarcinoma			•••••	•••••		•••••		•••••
.		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
	-	1/50 (2%)	0/50 (0%)	00.000/	.	1/50 (2%)	0/50 (0%)	00 40/
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Liver: Cholangioma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	00 0000		0/50 (0%)	0/50 (0%)	25. 22/
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 180

Report Date: 10/04/2007

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Liver: Hepatocellular Adenoma								
riepatocentiai Adenoma		2/50 (4%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	2/50 (4%) 0/50 (0%)	
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
*Liver: Hepatocellular Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma								
nepatocential Carcinoma	or riepatoc	2/50 (4%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	2/50 (4%) 0/50 (0%)	
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
Liver: Hepatocellular Carcinoma, Hepatoblastoma	Hepatocell	ular Adenoma, or						
		2/50 (4%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	2/50 (4%) 0/50 (0%)	
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 181

			Male				Female	
Lung: Alveolar/Bronchiolar A	Adenoma							
		4/50 (8%) 2/50 (4%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		4/50 (8%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	
Overall Incidence	Total	7/250 (2.8%)	Mean 2.8%	SD 3.35%	Total	5/200 (2.5%)	Mean 2.5%	SD 3.79%
Lung: Alveolar/Bronchiolar (Carcinoma							
		0/50 (0%) 2/50 (4%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/200 (0%)	Mean 0%	SD 0%
Adenoma Overall Incidence	Total	4/50 (8%) 4/50 (8%) 9/250 (3.6%)	0/50 (0%) 0/50 (0%) Mean 3.6%	1/50 (2%) SD 4.1%	Total	4/50 (8%) 0/50 (0%) 5/200 (2.5%)	1/50 (2%) 0/50 (0%) Mean 2.5%	SD 3.79%
Lung:		` ,				` ,		
Hemangiosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lung: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

E131011. OCI2001

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 182

			Male				Female	
Lung: Squamous Cell Carcinoma								
·		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
_ymph Node, Mesenteric: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		2/50 (4%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
Mammary Gland: Carcinoma					•••••			
Carcinoma		0/50 (0%)	` ,	0/50 (0%)		0/50 (0%)	0/50 (0%)	
verall Incidence	Tatal	0/50 (0%)	0/50 (0%) Mean 0%	CD 00/	Tatal	4/50 (8%)	2/50 (4%)	CD 2.020/
	Total	0/250 (0%)		SD 0%	Total	6/200 (3%)	Mean 3%	SD 3.83%
Mammary Gland: Carcinoma or Adenoma		2/52 (22)	2/22 (22)	. (50)		2/22 (40)	(00)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		2/50 (4%) 4/50 (8%)	1/50 (2%) 2/50 (4%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	9/200 (4.5%)	Mean 4.5%	SD 2.52%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 183

			Male				Female	
Mammary Gland: Fibroadenoma								
		2/50 (4%) 0/50 (0%)	2/50 (4%) 3/50 (6%)	0/50 (0%)		27/50 (54%) 26/50 (52%)	29/50 (58%) 24/50 (48%)	
overall Incidence	Total	7/250 (2.8%)	Mean 2.8%	SD 2.68%	Total	106/200 (53%)	Mean 53%	SD 4.16%
Mammary Gland: Fibroma						••••••		•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenon	na or Adenoma		- /					
		2/50 (4%) 0/50 (0%)	2/50 (4%) 3/50 (6%)	1/50 (2%)		28/50 (56%) 26/50 (52%)	30/50 (60%) 24/50 (48%)	
overall Incidence	Total	8/250 (3.2%)	Mean 3.2%	SD 2.28%	Total	108/200 (54%)	Mean 54%	SD 5.16%
Mammary Gland: Fibroma, Fibroadenon						•••••		•••••
		2/50 (4%) 0/50 (0%)	2/50 (4%) 3/50 (6%)	1/50 (2%)		28/50 (56%) 28/50 (56%)	30/50 (60%) 25/50 (50%)	
verall Incidence	Total	8/250 (3.2%)	Mean 3.2%	SD 2.28%	Total	111/200 (55.5%)	Mean 55.5%	SD 4.12%
Mesentery: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 184

			Male				Female	
#Mesentery: Hemangiosarcoma								
		0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Rhabdomyosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Nose:	•••••				•••••			
Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		1/50 (2%)	0/49 (0%)	0/30 (0/8)		0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/199 (0%)	Mean 0%	SD 0%
Nose: Chondroma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	
Overall Incidence	Total	0/30 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 185

			Male				Female	
*Nose: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Nose: Squamous Cell Carcino	oma	•••••	•••••	•••••		•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Papilloma Squamous o Overall Incidence	Total	1/50 (2%) 0/50 (0%) 2/250 (0.8%)	1/50 (2%) 0/50 (0%) Mean 0.8%	0/50 (0%) SD 1.1%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%
		,	Mean 0.8%			, ,	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Squamous Cell Carcino		/nx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma	Tongue, Phary							
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:10/04/2007

Page: 186

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

			Male				Female	
Oral Mucosa: Squamous Cell Carcino	ma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Oral Mucosa: Squamous Cell Papillon								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
overali incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	wear 0%	SD 0%
Ovary: Granulosa Cell Tumor E	Benign					0/50 (0%)	0/50 (0%)	
						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
Ovary:		•••••	• • • • • • • • • • • • • • • • • • • •	•••••		•••••		
Granulosa Cell Tumor N	/lalignant							
						0/50 (0%)	0/50 (0%)	
Overall Incidence					Tatal	0/50 (0%)	0/50 (0%)	CD 00/
verali incidence					Total	0/200 (0%)	Mean 0%	SD 0%
Ovary: Granulosa Cell Tumor: I								
		·,				0/50 (0%)	0/50 (0%)	
						0/50 (0%)	0/50 (0%)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 187

			Male		Female	
*Ovary: Granulosa-Theca Tumor Be	enign					
	_			0/50 (0		
Overall Incidence				0/50 (0 Total 1/200 (0.5%	,	
*Pancreas: Adenoma				-1		
		0/50 (0%) 1/49 (2%)	0/49 (0%) 0/49 (0%) 1/50 (2%)	0/50 (0' 0/50 (0'	%) 0/49 (0%) %) 0/49 (0%)	
Overall Incidence	Total	2/247 (0.81%)	Mean 0.81% SD 1.11%	•	Mean 0% SD 0%	
*Pancreas: Carcinoma						
- Caronia		0/50 (0%)	0/49 (0%) 0/49 (0%)	,	%) 0/49 (0%)	
O	T-1-1	0/49 (0%)	0/50 (0%)	(-	%) 0/49 (0%)	
Overall Incidence	Total	0/247 (0%)	Mean 0% SD 0%	Total 0/198 (0%)	Mean 0% SD 0%	
Pancreas: Carcinoma or Adenoma						
		0/50 (0%)	0/49 (0%) 0/49 (0%)	•	%) 0/49 (0%)	
Overell Incidence	Total	1/49 (2%)	1/50 (2%)	•	%) 0/49 (0%) Mean 0% SD 0%	
Overall Incidence	Total	2/247 (0.81%)	Mean 0.81% SD 1.11%		Mean 0% SD 0%	
*Pancreas: Mixed Tumor Benign						
		1/50 (2%)	0/49 (0%) 0/49 (0%)	0/50 (0		
Overall Incidence	Total	0/49 (0%)	0/50 (0%)	•	%) 0/49 (0%)	
Overall Incidence	Total	1/247 (0.4%)	Mean 0.4% SD 0.89%	Total 0/198 (0%)	Mean 0% SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 188

			Male				Female	
Parathyroid Gland:								
Addionia		0/49 (0%)	1/45 (2%)	1/46 (2%)		0/47 (0%)	0/48 (0%)	
	.	0/47 (0%)	1/48 (2%)	00 4 400/	.	0/49 (0%)	0/50 (0%)	00.00/
verall Incidence	Total	3/235 (1.28%)	Mean 1.3%	SD 1.18%	Total	0/194 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma Malignant	t							
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma: Benign, I	Malignant, NOS	3						
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Dista Adenoma		ied Site:						
		10/50 (20%)	10/50 (20%)	20/50 (40%)		17/50 (34%)	24/49 (49%)	
Overall Incidence	Total	9/50 (18%)	16/49 (33%) Mean 26.13%	CD 0.70/	Total	23/50 (46%)	29/48 (60%) Mean 47.35%	SD 10.85%
verali incidence	Total	65/249 (26.1%)		SD 9.7%	Total	93/197 (47.21%)		SD 10.85%
Pituitary Gland: Pars Dista Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	1/49 (2%) 0/48 (0%)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Sion. Oct2007

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 189

			Male				Female				
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma											
		10/50 (20%) 9/50 (18%)	10/50 (20%) 16/49 (33%)	20/50 (40%)		17/50 (34%) 25/50 (50%)	25/49 (51%) 29/48 (60%)				
verall Incidence	Total	65/249 (26.1%)	Mean 26.13%	SD 9.7%	Total	96/197 (48.73%)	Mean 48.86%	SD 10.96%			
Pituitary Gland: Pars Inte Adenoma											
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)				
verall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/197 (0%)	Mean 0%	SD 0%			
Pituitary Gland: Pars Inte	rmedia:										
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)				
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%			
ituitary Gland: Pars Inte	rmedia:			•••••							
Carcinoma or Adenom	na	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)				
verall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/197 (0%)	Mean 0%	SD 0%			
Prostate: Adenoma					•••••						
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)							
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%							

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

CISION: OCIZOO7

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 190

			Male	Female
*Prostate: Carcinoma or Adenoma		0/49 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/249 (0%)	0/50 (0%) Mean 0% SD 0%	
*Salivary Glands: Sarcoma				
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
*Salivary Glands: Schwannoma Malignant				
		1/49 (2%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.41% SD 0.91%	Total 0/200 (0%) Mean 0% SD 0%
#Skeletal Muscle: Fibrosarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
#Skeletal Muscle: Hemangioma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 191

			Male				Female	
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Lipoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma	•••••							
·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Skeletal Muscle:							•••••	
Rhabdomyosarcoma or	Rhabdomyom	a 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Vehicle: FEED

Page: 192

		Male				Female	
	0/50 (0%) 0/50 (0%)		0/50 (0%)				
Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
	•••••		•••••				
Basosquamou	s Tumor Benian						
	0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	
Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
sosquamous	Tumor Benign, or 0/50 (0%) 1/50 (2%)	1/50 (2%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	
Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	2/200 (1%)	Mean 1%	SD 1.15%
				•••••	•••••		
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	
Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Basosquamo	us Tumor (malignant or	······································					
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	
Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
	Total Total Total Total	Total 2/250 (0.8%) Basosquamous Tumor Benign 0/50 (0%) 0/50 (0%) Total 2/250 (0.8%) Sosquamous Tumor Benign, or 0/50 (0%) 1/50 (2%) Total 3/250 (1.2%) O/50 (0%) 0/50 (0%) Total 0/250 (0%) Basosquamous Tumor (malignant or 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%) Total 2/250 (0.8%) Mean 0.8% Basosquamous Tumor Benign 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%) Total 2/250 (0.8%) Mean 0.8% Bosquamous Tumor Benign, or 0/50 (0%) 1/50 (2%) 1/50 (2%) 1/50 (2%) Total 3/250 (1.2%) Mean 1.2% 0/50 (0%) 0/50 (0%) Total 0/250 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% Basosquamous Tumor (malignant or 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	O/50 (0%) 1/50 (2%) 0/50 (0%) Total 2/250 (0.8%) Mean 0.8% SD 1.1% Basosquamous Tumor Benign	O/50 (0%)	O/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (2%) 1/50 (0%) 1/50 (0%) 1/50 (0%) 1/50 (2%) 1/50	0/50 (0%) 1/50 (2%) 1/50 (2%) 1/50

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

rsion. Oct2007

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 193

			Male				Female	
#Skin: Basal Cell Carcinoma, I Tumor (benign, maligna								
(0 / 0	,	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Tatal	1/50 (2%)	1/50 (2%)	CD 4.40/	Tatal	2/50 (4%)	1/50 (2%)	CD 4.040/
overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
Skin: Basal or Sq. Cell Carcir or B), Basal Cell Adeno Papilloma, Keratoacant	ma, Adenoma,	Papilloma, Sq	4/50 (8%)	1/50 (2%)		3/50 (6%)	0/50 (0%)	
		2/50 (4%)	3/50 (6%)	1/30 (2/0)		2/50 (4%)	2/50 (4%)	
Overall Incidence	Total	21/250 (8.4%)	Mean 8.4%	SD 7.92%	Total	7/200 (3.5%)	Mean 3.5%	SD 2.52%
Skin: Fibroma Overall Incidence	Total	5/50 (10%) 2/50 (4%) 20/250 (8%)	4/50 (8%) 8/50 (16%) Mean 8%	1/50 (2%) SD 5.48%	Total	3/50 (6%) 1/50 (2%) 5/200 (2.5%)	0/50 (0%) 1/50 (2%) Mean 2.5%	SD 2.52%
Skin: Fibroma, Fibrosarcoma Fibrous Histiocytoma		6/50 (12%) 2/50 (4%)	4/50 (8%) 8/50 (16%)	4/50 (8%)		4/50 (8%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	24/250 (9.6%)	Mean 9.6%	SD 4.56%	Total	6/200 (3%)	Mean 3%	SD 3.46%
Skin: Fibrosarcoma		0/50 (/0//)	0/50 (0%)	2/50 (49/)		1/50 /29/\	0/50 (09/)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	2/50 (4%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
		0,00 (0,0)	3/33 (3/3)			3,33 (3,73)	3/00 (0/0)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 194

			Male				Female	
#Skin: Fibrosarcoma, Sarcoma Histiocytoma	a, Myxosarcom	a, or Fibrous						
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	3/50 (6%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 2.61%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Fibrous Histiocytoma							•••••	
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00)	•••••	0/50 (00)	0/50 (00/)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma								
		10/50 (20%) 1/50 (2%)	3/50 (6%) 1/50 (2%)	1/50 (2%)		3/50 (6%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	16/250 (6.4%)	Mean 6.4%	SD 7.8%	Total	3/200 (1.5%)	Mean 1.5%	SD 3%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 195

			Male				Female	
#Skin: Lipoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin:					•••••			
Neurofibroma or Schwa	annoma benign	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin:						•••••	•••••	
Neurofibrosarcoma or	Schwannoma (r	nalignant or NOS) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 196

			Male				Female				
#Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)											
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%			
#Skin: Osteosarcoma											
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%			
#Skin: Sarcoma											
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%			
#Skin: Schwannoma Benign											
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%			
#Skin: Schwannoma Malignant											
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 197

			Male				Female	
#Skin: Squamous Cell Carcin	oma							
- 4		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcin								
Basosquamous Tumor	(mangham or r	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Squamous Cell Papillo	oma							
·		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Squamous Cell Papillo	ma or Papillom	a						
	•	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Squamous Cell Papillo Carcinoma or Keratoad	oma, Papilloma,							
		11/50 (22%) 1/50 (2%)	3/50 (6%) 2/50 (4%)	1/50 (2%)		3/50 (6%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	18/250 (7.2%)	2/50 (4%) Mean 7.2%	SD 8.44%	Total	4/200 (2%)	Mean 2%	SD 2.83%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 198

			Male				Female	
#Skin: Squamous Cell Papilloma	. Papilloma.	or Keratoacanthoma						
	, ,	11/50 (22%) 1/50 (2%)	3/50 (6%) 1/50 (2%)	1/50 (2%)		3/50 (6%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	17/250 (6.8%)	Mean 6.8%	SD 8.67%	Total	4/200 (2%)	Mean 2%	SD 2.83%
#Skin: Trichoepithelioma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 199

			Male				Female	
#Spinal Cord: Astrocytoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Fibrosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Spleen: Hemangioma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Spleen:			•••••					
Hemangiosarcoma		0/50 (0%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/49 (0%) 1/248 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%
Spleen: Leiomyosarcoma								
-		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/49 (0%) 1/248 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#Stomach, Forestomach: Leiomyosarcoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	1/30 (2/0)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Schwannoma Malignant	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incluence	TOTAL	0/250 (0%)	Medii 0%	3D 0%	TOtal	0/200 (0%)	Weall 0%	30 0%
#Stomach, Forestomach: Squamous Cell Carcinoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#01					•••••			
#Stomach, Forestomach: Squamous Cell Carcinoma	or Panillon	na Squamous						
oquamous con caromoma	o upo	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (00/)	0/50 (00/)	0/50 (00)		0/50 (00/)	0/50 (00/)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 200

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 201

			Male				Female	
#Stomach, Glandular: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Lipoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Testes: Adenoma								
		45/50 (90%) 48/50 (96%)	46/50 (92%) 46/50 (92%)	49/50 (98%)				
Overall Incidence	Total	234/250 (93.6%)	Mean 93.6%	SD 3.29%				
Thymus:								
Sarcoma		0/48 (0%)	0/48 (0%)	0/47 (0%)		0/50 (0%)	0/46 (0%)	
Overall Incidence	Total	0/48 (0%) 0/239 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/191 (0%)	0/47 (0%) Mean 0%	SD 0%
Thymus: Thymoma Benign	•••••							
		0/48 (0%) 0/48 (0%)	0/48 (0%) 0/48 (0%)	0/47 (0%)		0/50 (0%) 0/48 (0%)	0/46 (0%) 0/47 (0%)	
Overall Incidence	Total	0/239 (0%)	Mean 0%	SD 0%	Total	0/191 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 202

			Male		Fem	ale
Thymus: Thymoma Malignant						
		0/48 (0%) 0/48 (0%)	0/48 (0%) 0/4 0/48 (0%)	7 (0%)	0/50 (0%) 0/46 0/48 (0%) 0/47	(0%) (0%)
Overall Incidence	Total	0/239 (0%)	` '	SD 0% Total	()	n 0% SD 0%
Thymus:						
Thymoma: Benign, Malignant	, NOS	0/48 (0%)	0/48 (0%) 0/4	7 (0%)	0/50 (0%) 0/46	(09/)
		0/48 (0%) 0/48 (0%)	0/48 (0%) 0/4	7 (0%)	0/50 (0%) 0/46 0/48 (0%) 0/47	(0%) (0%)
overall Incidence	Total	0/239 (0%)	Mean 0%	SD 0% Tot	al 0/191 (0%) Mea	n 0% SD 0%
Thyroid Gland: C-Cell: Adenoma						
		10/50 (20%)	5/50 (10%) 6/5	0 (12%)	4/50 (8%) 3/49	(6%)
verall Incidence	Total	9/48 (19%) 41/245 (16.73%)	11/47 (23%) Mean 16.83%	SD 5.63% Tot	9/49 (18%) 10/47 al 26/195 (13.33%) Mea	(21%) n 13.44% SD 7.5%
Γhyroid Gland: C-Cell: Carcinoma						
Garcinoma		1/50 (2%) 1/48 (2%)	4/50 (8%) 1/5 0/47 (0%)	0 (2%)	0/50 (0%) 1/49 0/49 (0%) 1/47	(2%) (2%)
verall Incidence	Total	7/245 (2.86%)	` '	SD 3.03% Total	` '	n 1.04% SD 1.2%
Thyroid Gland: C-Cell: Carcinoma or Adenoma						
		11/50 (22%)	9/50 (18%) 7/5	0 (14%)	4/50 (8%) 4/49	(8%)
Verall Incidence	Total	10/48 (21%) 48/245 (19.59%)	11/47 (23%) Mean 19.65%	SD 3.73% Total	9/49 (18%) 11/47 al 28/195 (14.36%) Mea	(23%) n 14 48% SD 7 67%
Overall Incidence	Total	48/245 (19.59%)	Mean 19.65%	SD 3.73% Total	al 28/195 (14.36%) Mea	n 14.48% SD 7.67%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 203

			Male				Female	
*Thyroid Gland: Follicular Cell: Adenoma								
		2/50 (4%) 1/48 (2%)	2/50 (4%) 0, 0/47 (0%)	/50 (0%)		0/50 (0%) 0/49 (0%)	0/49 (0%) 2/47 (4%)	
Overall Incidence	Total	5/245 (2.04%)	Mean 2.02%	SD 2%	Total	2/195 (1.03%)	Mean 1.06%	SD 2.13%
Thyroid Gland: Follicular Cell: Carcinoma	•••••				•••••			
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0, 0/47 (0%)	/50 (0%)		0/50 (0%) 1/49 (2%)	0/49 (0%) 0/47 (0%)	
Overall Incidence	Total	0/245 (0%)	Mean 0%	SD 0%	Total	1/195 (0.51%)	Mean 0.51%	SD 1.02%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		2/50 (4%) 1/48 (2%)	2/50 (4%) 0, 0/47 (0%)	/50 (0%)		0/50 (0%) 1/49 (2%)	0/49 (0%) 2/47 (4%)	
Overall Incidence	Total	5/245 (2.04%)	Mean 2.02%	SD 2%	Total	3/195 (1.54%)	Mean 1.57%	SD 2.03%
Tissue NOS: Fibrosarcoma								
i ibi odal doma		0/50 (0%)	()	/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%
Tissue NOS: Leiomyoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 204

			Male				Female	
#Tissue NOS: Lipoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/30 (0/6)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
†Tissue NOS: Paraganglioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
			•••••		• • • • • • • • • • • • • • • • • • • •			
Tissue NOS: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%)	0/50 (0%)	CD 0.000/	Total	0/50 (0%)	0/50 (0%)	CD 00/
	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
Tissue NOS:								
Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	,		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Tongue: Liposarcoma								
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/200 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

		Male				Female	
na or Papillon	na Squamous						
·	1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/200 (0%)	Mean 0%	SD 0%
ıa							
	` ,		0/50 (0%)			` ,	
Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/200 (0%)	Mean 0%	SD 0%
	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	
Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
	0/50 (0%) 0/50 (0%)		0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	
Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
	0/50 (0%)		1/49 (2%)		0/50 (0%)	0/50 (0%)	
Total	0/50 (0%) 1/248 (0.4%)	0/49 (0%) Mean 0.41%	SD 0.91%	Total	1/199 (0.5%)	0/49 (0%) Mean 0.5%	SD 1%
	Total Total Total	0/50 (0%) Total 2/250 (0.8%) a	Total 2/250 (0%) 0/50 (0%) Total 2/250 (0.8%) Mean 0.8% 1/50 (2%) 0/50 (0%) Total 2/250 (0.8%) Mean 0.8% 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) Total 2/250 (0.8%) Mean 0.8% 1/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) Total 0/248 (0%) Mean 0%	na or Papilloma Squamous 1/50 (2%) 1/50 (2%) 0/50 (0%) Total 2/250 (0.8%) Mean 0.8% SD 1.1% a 1/50 (2%) 1/50 (2%) SD 1.1% a 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 2/250 (0.8%) Mean 0.8% SD 1.1% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% SD 0% Total 0/248 (0%) Mean 0% SD 0% 0/50 (0%) 0/49 (0%) Total 0/248 (0%) Mean 0% SD 0%	na or Papilloma Squamous 1/50 (2%) 1/50 (2%) 0/50 (0%) Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total 1/50 (2%) 1/50 (2%) SD 1.1% Total 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% SD 0% Total 0/50 (0%) 0/50 (0%) 0/49 (0%) Total 0/248 (0%) Mean 0% SD 0% Total	na or Papilloma Squamous 1/50 (2%) 1/50 (2%) 0/50 (0%) Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total 0/200 (0%) 1/50 (0%) 1/50 (2%) 0/50 (0%) Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total 0/200 (0%) 1/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 1/50 (0%) Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total 0/200 (0%) Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total 0/200 (0%) Total 0/250 (0%) 0/50 (0%) 1/50 (0%)	na or Papilloma Squamous 1/50 (2%) 1/50 (2%) 0/50 (0%) Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total 0/200 (0%) 0/50 (0%) Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total 0/200 (0%) Mean 0% 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total 0/200 (0%) Mean 0% 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 2/250 (0.8%) Mean 0.8% SD 1.1% Total 0/200 (0%) Mean 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/250 (0%) 0/49 (0%) 0/49 (0%) Total 0/248 (0%) Mean 0% SD 0% Total 0/199 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 205

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 206

Report Date: 10/04/2007

Length of Study: CHRONIC

			Male				Female	
*Urinary Bladder: Leiomyosarcoma								
, , , , , , , , , , , , , , , , , , , ,		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	1/49 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)	
Overall Incidence	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
#Uterus: Adenoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus:					• • • • • • • • • • • • • • • • • • • •			
Carcinoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
#Uterus: Deciduoma Benign								
•						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence					Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F344 **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 207

Report Date: 10/04/2007

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Hemangioma 0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Uterus: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Uterus: Leiomyoma (0%)0/50 (0%)0/50 (0%) 0/50 (0%)**Overall Incidence** SD 0% Total 0/200 Mean 0% **#Uterus: Polyp Stromal** (12%)(20%)8/50 (16%)(32%)**Overall Incidence** (20%)Mean 20% SD 8.64% Total 40/200 **#Uterus:** Sarcoma Stromal (0%)0/50 (0%)(2%)**Overall Incidence** Total 1/200 (0.5%)Mean 0.5% SD 1%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 208

Report Date: 10/04/2007

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Sarcoma Stromal or Polyp Stromal (12%)(20%)(34%) 8/50 (16%)17/50 **Overall Incidence** Total 41/200 (20.5%) Mean 20.5% SD 9.57% #Uterus: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Vagina: Polyp 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/200 Mean 0% #Vagina: Sarcoma (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Mean 0% SD 0% Total 0/200 (0%) #Zymbal's Gland: Adenoma (0%)(0%)0/50 0/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%)Mean 0% SD 0% Total 0/200 (0%)Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 209

			Male				Female	
#Zymbal's Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 3/50 (6%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 2.61%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 3/50 (6%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 2.61%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied